

REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested.

Status of the Claims

Claims 1-15 are presented. Claims 1 and 5 are amended to include a Markush group of cosmetic auxiliaries and/or additives as component (b). Support is found throughout the specification as originally filed, as well as in original claim 6, now cancelled. Claim 6 is cancelled without prejudice. New claims 12-15, directed to a method of protecting human skin from the effects of ageing and/or reversing the effects of ageing in human skin, are added. Support is found in the specification as originally filed, *inter alia*, on page 8, lines 4-5. Claims 9-11 were previously withdrawn as being drawn to a non-elected invention.

No new matter has been introduced.

Summary of the Invention as Claimed

One aspect of the invention as now claimed is drawn to a composition comprising (a) a supercritical solvent extract of the fruit of *Schisandra chinensis*, or a component thereof comprising a Markush group of specific compounds; and (b) at least one cosmetic auxiliary and/or additive selected from a Markush group of art-recognized cosmetic auxiliaries and/or additives (claims 1 and 5). Note that the Markush group of (b) does not include hydrotropes.

A second aspect of the presently claimed invention is drawn to a method of protecting human skin from the effects of ageing and/or reversing the effects of ageing in human skin, both of which are broadly characterized as anti-ageing effects. Said method comprises applying to the skin a composition comprising a supercritical solvent extract of the fruit of *Schisandra chinensis* (claim 12).

Rejections under 35 U.S.C. § 112, second paragraph

Previously pending claim 6 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite since component (b) was disclosed in the singular form, whereas the last

component of the Markush group, “combinations of two or more”, suggested a plural component, not a singular one.

Claim 6 has been cancelled in the present reply, thereby mooted the Examiner’s objection; however, a similar Markush group has been incorporated into both claims 1 and 5 as presently amended, and new claim 15, necessitating a response to the Examiner’s argument.

It is well understood in the art that a “component” of a Markush group may be a mixture or combination (MPEP 2173.05(h)). Further, the language “at least one” as applied to component (b) implies that there may be **more** than one cosmetic auxiliary/additive. Therefore, the Markush mixture is appropriate as currently presented in claims 1, 5 and 15.

Rejections under 35 U.S.C. § 102(b)

Previously pending claims 1-8 were rejected under 35 U.S.C. § 102(b) as being anticipated by Kim et al. (J. Chromatographic Science, 1999, 37, 457-461; “Kim”). Applicants respectfully traverse the rejection.

Kim discloses the effect of the plant matrix (leaves vs. stems vs. fruit) of Schisandra chinensis on the efficiency of supercritical fluid extraction with supercritical CO₂, with and without cosolvent ethanol. The Examiner stated that ethanol is an auxiliary. However, as presently amended, the Markush group of component (b) of claims 1 and 5 does not include hydrotropes, which would include lower alcohols, and no other cosmetic auxiliary/additive of applicants’ Markush group is disclosed by Kim. Thus, Kim does not include component (b), as presently amended, and therefore does not include each and every limitation of the claims in a single reference. Therefore Kim is an improper 102(b) reference for the claims as presently amended.

In view of the above amendments and remarks, the Examiner is respectfully requested to withdraw the anticipation rejection.

Rejections under 35 U.S.C. § 102(b) and/or 103(a)

Previously pending claims 1-8 were rejected under 35 U.S.C. § 102(b) as being anticipated, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over Ikeda et al. (JP 06279256, English abstract; "Ikeda") in view of Newmark et al. (US 6,242,012; "Newmark"). Applicants respectfully traverse the rejection.

Ikeda discloses a skin care cosmetic containing, *inter alia*, Gomishi (*Schisandracea* Fructus) extract in a lotion or o/w cream. In the example disclosed in the English abstract, the extract was prepared by water extraction at room temperature for 7 days.

Newmark discloses an herbal composition for promoting hormonal balance in women, containing, *inter alia*, either regular (i.e. aqueous and/or alcoholic) extracts or supercritical solvent extracts of Schizandra (*Schisandra*) berries. There is no recognition of any special advantage of the supercritical solvent extract of *Schisandra chinensis*. Further, Newmark states that the **preferred** extract of *Schisandra chinensis* is the **regular** extract, even though specifying supercritical solvent extracts of ginger, rosemary and evening primrose oil. Thus, Newmark fails to recognize the unique effects of the supercritical solvent extract of *Schisandra chinensis*, as disclosed by applicants. Further, there is no disclosure in Newmark relating to anti-ageing effects of *Schisandra chinensis*. One skilled in the art reading Newmark, with or without Ikeda, would not be led to applicants' specific composition and method, without the benefit of applicants' present disclosure.

Still further, the Examiner stated that

"Applicant argues that there is unexpected superior performance from supercritical extraction. In response to Applicants' argument, there is no data to support the allegation. Applicant need [sic] to show that supercritical extract of *Schisandra chinensis* is better than other types of *Schisandra chinensis* extract. Thus, unexpected result is unpersuasive." (Final Office Action, page 7, middle)

In response, submitted herewith is the Rule 1.132 declaration of Marie-France Zambaux, detailing experiments designed to compare a regular aqueous extract of *Schisandra chinensis* fruit versus a supercritical carbon dioxide extract. In summary, there is a clear and dramatic difference in the performance of an aqueous extract versus a supercritical carbon dioxide extract with regard to its regenerating and revitalizing activities on human fibroblasts cultured

in vitro. The comparative data clearly showed that the supercritical carbon dioxide extract significantly enhanced the levels of cellular proteins, ATP and DNA in a dose-dependent manner. Such *in vitro* activities are recognized by skilled artisans as representative of anti-ageing effects *in vivo*. In contrast, the aqueous extract showed no statistically significant effect on the same parameters, except for ATP, which actually showed a statistically significant dose-independent decrease.

Thus, on the basis of the newly submitted data, the advantages of a supercritical solvent extract of *Schisandra chinensis* are apparent with regard to parameters relating to anti-ageing effects.

In view of these arguments and supporting data, the Examiner is respectfully requested to withdraw the rejections.

Rejections under 35 U.S.C. § 103(a)

Previously pending claims 1-8 were rejected under 35 U.S.C. § 103(a) as being obvious over Newmark in view of Kim. Applicants respectfully traverse the rejection.

Previously pending claims 1-8 were rejected under 35 U.S.C. § 103(a) as being obvious over Sung et al. (WO 01/41778; "Sung") and Newmark in view of Kim. Applicants respectfully traverse the rejection.

Newmark and Kim are discussed above.

Sung discloses the melanin synthesis inhibitory effect of gomisin N and gamma-schizandrin. There is no disclosure in Sung related to anti-ageing effects of either the constituent chemicals or *Schisandra chinensis* extract.

As above, in view of the comparative data provided in the Rule 1.132 declaration, applicants' supercritical solvent extract is distinguished as novel and patentably unobvious with regard to the biological parameters relating to anti-ageing effects.

In view of these arguments and supporting data, the Examiner is respectfully requested to withdraw the rejections.

Conclusion

In summary, in view of the above claim amendments and remarks, together with the Declaration of Marie-France Zambaux submitted herewith, applicants believe that all of the pending claims as amended are in condition for allowance. The Examiner is respectfully requested to reconsider, withdraw the rejections and allow the claims.

If any additional fees are required in support of this application, authorization is granted to charge our Deposit Account No. 50-1943.

Respectfully submitted,

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